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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,862	01/03/2007	Steven Kritzler	65428(70403)	9130

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EXAMINER
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KOSAR, AARON J

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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11/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/576,862	<b>Applicant(s)</b> KRITZLER ET AL.	
	<b>Examiner</b> AARON J. KOSAR	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-25 in the reply filed on June 11, 2009 is acknowledged. The traversal is on the ground(s) that it would not be burdensome to search the inventions together. This is not found persuasive because the Invention groups are drawn to different classes of invention wherein unity of invention was shown to be lacking, and thus the restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-26 are pending of which claim 26 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 11, 2009.

Claims 1-25 have been examined on their merits.

### ***Specification***

The use of the trademarks "LUHTENSOL", "BRONOPOL/CAMPRES BNPD", "SAVINASE 0.9T", "GOHSENOL N-500", and "GOHSENOL G105" have been noted in this application (for example page 5, table and line 14, 15; page 6, lines 27-28). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

Claim 6 is objected to because of the following informalities:

In claim 6, line 2, the phrase “proteolytic and hydrolase” is internally inconsistent. If Applicant intends for either “proteolytic and hydrolytic” or “protease and hydrolase”, then the claim should so recite.

Appropriate correction is suggested.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high molecular weight" in claims 4 and 5 is a relative term which renders the claim indefinite. The term "high" and “high molecular weight” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case one would not be apprised as to the metes and bounds of which compounds are included and/or excluded by the terms. Clarification is required.

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Claim 5 recites the term “appropriate” in line 4; however, the metes and bounds of which compounds qualify or are disqualified as being "appropriate" or how one would determine an appropriate- versus an inappropriate-hydrophobe is not defined by the claims or specification, and thus one would not be apprised as to which compounds are included and/or excluded by the term. Clarification is required.

Claim 5 recites “surfactant compounds” in line 2; however claim 4 line 5 recites a surfactant and it is unclear if the surfactants are the same or different surfactants. Clarification is required.

Claim 25 recites the phrase “when provided with slow release encapsulation”; however, it is unclear if the “slow-release encapsulation” is another product or a further limitation of the tablet. Furthermore, the claim recites “when provided” which renders the claim indefinite, because it is unclear if encapsulation is required by the claim or merely exemplary. Clarification is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scialla (EP 0 619 367 A1).

Scialla beneficially teaches the combination of (i) an excipient, (ii) a biocide, (iii) an enzyme, and (iv) an enzyme preserving means by teaching a composition comprising (i) filler (an excipient), for example sodium sulphate (page 3, lines 36-40); (ii) a source of peroxide (a biocide) and/or sodium persulphate and perborates (a boron compound) (for example, page 3, lines 48-58); (iii) an enzyme, including amylase, cellulase, lipase or protease (for example, page 2, lines 46-49; page 3, ¶2); and (iv) enzyme stabilizers (a preserving means), for example calcium salts (for example, page 3, lines 34-35) or acid/alkali (for example, page 4, lines 14-18). Scialla also teaches providing additional components, including a surfactant (for example, page 3, lines 21-35) further including any fatty alcohol, fatty acid alkanolamides, polyethylglycol ethers, polyethyleneglycol with molecular weight 1000 to 80000, and C<sub>6</sub>-C<sub>24</sub> amine oxide surfactants (for example, page 3, lines 31-33); and obtaining the composition from compression/extrusion (for example, page 4, lines 38-41).

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Scialla does not teach a period of 3, 6, or 12 months in water or a composition having a combination of the components having the instantly-claimed amounts (ppm, % by weight).

Scialla also does not teach the product made in a tablet press or by the process of moulding.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have provided the composition of Scialla, in an amount as instantly-claimed or having incomplete dissolution in water for the period of time as instantly-claimed, based upon the overall beneficial teaching provided by Scialla. If not expressly taught by Scialla, this reference with respect to the amounts and proportions of the components relative to each other (see whole document, for example 500 ppm active oxygen/peroxide (page 3, line 49)) and in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining one or more suitable absolute or relative amount/quantity of a component in which to provide such a composition), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please note, the instantly-claimed composition does not rigorously require any absolute amount of tablet or an amount of water relative to said amount of tablet, and thus the prior art of Scialla still embraces amounts having the claimed degree of incomplete solubility (e.g. high concentration of tablet components, low volume of water, and including amounts/concentrations beyond the solubility limit of the components therein).

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Although Scialla does not teach expressly the product made by extrusion, moulding, or in a tablet press, the product of Scialla comprises a tablet (composition) which appears to be otherwise obvious over the instantly claimed tablet (composition), and thus appears to be the same composition though made by a different process. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. (see MPEP § 2113).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Please note, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/  
Examiner, Art Unit 1651

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655